Practitioner's Docket No. 021218.0009US2 ***PATENT***

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Gin Wu

Application No.: 10/662,744
Filed: 09/15/03
For: Hard Tissue Drug Delivery Device and Method

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Gin Wu

Application No.: 10/662,744 Group No.: 3767
Filed: 09/15/2003 Examiner: MacNeil, Elizabeth
For: Hard Tissue Drug Delivery Device and Method

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Commissioner for Patents
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Alexandria, VA 22313-1450

TRANSMITTAL OF APPEAL BRIEF
(PATENT APPLICATION--37 C.F.R. § 41.37)

1. Transmitted herewith, is the APPEAL BRIEF in this application, with respect to the Notice of Appeal filed on February 6, 2008.

2. STATUS OF APPLICANT

This application is on behalf of a small entity. A statement was already filed.

3. FEE FOR FILING APPEAL BRIEF

Pursuant to 37 C.F.R. § 41.20(b)(2), the fee for filing the Appeal Brief is:

small entity	$255.00
Appeal Brief fee due	**$255.00**

4. EXTENSION OF TERM

The proceedings herein are for a patent application and the provisions of 37 C.F.R. § 1.136 apply.

Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

5. TOTAL FEE DUE

The total fee due is:

Appeal brief fee	$255.00
Extension fee (if any)	$0.00
TOTAL FEE DUE	**$255.00**

6. FEE PAYMENT

Authorization is hereby made to charge the amount of $255.00 to Deposit Account No. 500341.

A duplicate of this transmittal is attached.

7. FEE DEFICIENCY

If any additional extension and/or fee is required, and if any additional fee for claims is required, charge Deposit Account No. 500341.

Date: April 7, 2008

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
GROUP ART UNIT 3767

EXAMINER:	Elizabeth MacNeill
APPELLANT:	Gin Wu
SERIAL NO:	10/662,744
FILED:	September 15, 2003
FOR:	Hard Tissue Drug Delivery Device and Method

MS Appeal Brief – Patents
Commissioner of Patents and Trademarks
Washington, D.C. 20231
Attention: Board of Patent Appeals and Interferences

APPELLANT'S BRIEF UNDER 37 CFR §41.37

This brief is filed on April 7, 2008, following the Appellant's Notice of Appeal filed on February 6, 2008.

The fees required under §1.17 and any required petition for extension of time for filing this brief and fees therefore, are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief contains the following items under the headings in the order indicated:

I. Real Party In Interest

II. Related Appeals and Interferences

III. Status of Claims

IV. Status of Amendments

V. Summary Of Claimed Subject Matter

VI. Ground of Rejection To Be Reviewed On Appeal

VII. Argument

VIII. Claims Appendix

IX. Evidence Appendix

X. Related Proceedings Appendix

I. Real Party In Interest

The real party in interest is the assignee, Pro-Dex, Inc.

II. Related Appeals and Interferences

There are no other appeals or interferences in this matter known to appellant.

III. Status of Claims

1. Claims pending: 14-23
2. Claims cancelled: 1-13, and 24.
3. Claims rejected: 14-23.
4. Claims on appeal: 14-23.

IV. Status of Amendments

No amendments were filed after final rejection. The claims were rejected in the final Office Action mailed 11/8/2007 based on amendments and arguments entered responding to non-final Office Action mailed 10/23/2007. Section IX recites the claims as entered/pending and under final rejection.

V. Summary of Claimed Subject Matter

The pending claims generally recite a hollow drill bit for drilling hard tissue and injecting medication and a method of using the drill bit. (See e.g. Abstract, P3/L21-28, P5/L1-5, P8/L21-23, P11/L4-6). The drill bit has a shaft with a lumen that connects two openings, and a cutting

edge. (See e.g. Abstract, P3/L21-23, P8/L21-25, P9/L20-26) In order to prevent the lumen from becoming clogged, an open notch in the shaft has a length greater than a diameter of the lumen, and the length from the distal tip of the cutting surface to the proximal end of the notch is greater than the thickness of the hard tissue. (See e.g. Abstract, P4/L8-19, P9/L10-24)

A) **Independent Claim 14** recites a drill bit for drilling hard tissue and injecting medication comprising: (See e.g. Abstract, P3/L21-28, P5/L1-5, P8/L21-23, P11/L4-6)

a shaft having a proximal end with a first opening, a distal end with a second opening and a beveled cutting surface; (See e.g. P3/L21-P4/L7, P8/L21-25, P9/L20-26)

a lumen inside the shaft that extends between first and second openings, and that receives debris entering the first opening as a result of operation of the cutting surface; (See e.g. Abstract, P3/L21-P4/L7, P5/L22-23, P10/L27-P11/L4)

an open notch disposed in the shaft, and having a length greater than a diameter of the lumen; and (See e.g. P4/L1-28, P9/L21-30, P11/L16-20)

wherein an overall length from a distal tip of the cutting surface to a proximal end of the open notch is greater than a thickness of the hard tissue. (See e.g. P3/L21-27, P9/L10-30)

B) **Dependent Claim 19** recites a method of injecting a substance into a bone, comprising: (See e.g. Abstract, P3/L21-28, P5/L1-5, P8/L21-23, P11/L4-6)

using a drill bit according to claim 14 to drill a hole in the bone; and (P5/L28-29, P10/L5-26, P11/L11-20, P12/L9-13)

injecting the substance into the proximal opening. (P3/L12-17, P4/L3-7, P5/L3-5, P6/L12-15, P10/L16-21, P12/L3-6)

VI. Grounds of Rejection to be Reviewed on Appeal

1. Rejection of claims 14, 15, 17, 18, 22, and 23 under 35 U.S.C. 102(b) as being anticipated by De Santis (US 5,560,373).

2. Rejection of claims 14, 15, 17, 19, and 21 under 35 U.S.C. 102(b) as being anticipated by Shaw (US 5,261,818).

3. Rejection of claims 16 and 20 under 35 U.S.C. 103(a) as being obvious over Shaw.

VII. Argument

On **June 8, 1999**, the Applicant filed provisional application no. 60/138,095 for a Hard Tissue Drug Delivery Device and Method.

On **June 6, 2000**, the Applicant filed application no. 09/588,425 claiming the benefit of the provisional application.

On **September 15, 2003**, the Applicant filed a continuation with application no. 10/662,744, claiming the benefit of both the provisional application and the parent application.

On **September 20, 2006**, the Applicant filed a preliminary amendment to cancel all original claims 1-13, and add new claims 14-21.

On **October 11, 2006**, the Office issued a Non-Final Rejection, rejecting all claims 14-21. The Office rejected claims 14-21 under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement, arguing that the limitation of a third opening was not supported by the specification. The Office also rejected claims 14-21 under 35 U.S.C. 102(b) as being anticipated by U.S. 6,135,769 to Kwan.

On **January 2, 2007**, the Applicant filed a response to the Office Action dated October 11, 2006. The Applicant amended the claims to remove references to a third opening, clarified that the beveled cutting surface comprises a slot and not a third opening, and added claims 22-24 to claim additional embodiments of the invention. Additionally, the Applicant argued that while Kwan teaches a drill bit with a beveled distal end, the cutting surface of Kwan does not have a slot where debris easily exits the slot.

On **February 16, 2007**, the Office issued a Final Rejection, rejecting all claims 14-24. The Office rejected claim 24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim "the slot through which at least some debris exits from the shaft." The Office also rejected claims 14-23 under 35 U.S.C. 102(e), again as being anticipated by Kwan.

On **May 16, 2007**, the Applicant filed a response to the Office Action dated February 16, 2007. The Applicant cancelled claim 24, and amended the independent claim to clarify that the shaft

has an extended open slot with a length greater than a diameter of the lumen. The Applicant argued that while Kwan teaches a drill bit with a beveled distal end and an opening for debris to exit, the opening is not a slot, nor is the opening extended to form a slot. Additionally, Kwan teaches away from using an extended slot.

On **July 23, 2007**, the Office issued a Non-Final Rejection, again rejecting claims 14-23. The Office rejected claims 14, 15, 17, 18, 22, and 23 under 35 U.S.C. 102(b) as being anticipated by US 5,560,373 to De Santis, claims 14, 15, 17, and 19-23 under 35 U.S.C. 102(b) as being anticipated by US 5,261,818 to Shaw, and claim 16 under 35 U.S.C. 103(a) as being obvious over De Santis.

On **October 23, 2007**, the Applicant filed a response to the Office Action dated July 23, 2007. The Applicant amended claim 14 to clarify that the drill bit drills hard tissue and injects medication, and that the overall length from the distal tip of the cutting surface to the proximal end of the open notch is greater than a thickness of the hard tissue. Applicant argued that neither De Santis nor Shaw teaches drill bits with an overall length from the tip of the cutting surface to the end of the open notch that is greater than the thickness of the tissue being drilled. Additionally, De Santis does not teach a drill bit that injects any medication, while Shaw does not teach a lumen that receives debris.

On **November 8, 2007**, the Office issued a Final Rejection, again rejecting claims 14-23. The Office argued that intended use limitations are only effective if they result in a structural difference between the prior art and the claimed invention. The Office argued that comparing the overall length of the drill bit to the thickness of the hard tissue is an intended use limitation, and that injecting medication is also an intended use limitation that does not affect the structure of the claimed invention. The Office also argued that while Shaw does not teach that the lumen receives debris, lose debris can still become lodged in the lumen of Shaw.

On **February 6, 2008**, the Applicant filed a Notice of Appeal.

On **April 7, 2008**, the Applicant filed this Appeal Brief.

ARGUMENT

A. REJECTION OF DE SANTIS CLAIMS 14, 15, 17, 18, 22, AND 23 UNDER 35 U.S.C. 102(B) AS BEING ANTICIPATED BY DE SANTIS

The Office's rejection of claims 14, 15, 17, 18, 22, and 23 under 35 U.S.C. 102(b) as being anticipated by De Santis (US 5,560,373) should be withdrawn.

The Office argued that "a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim."

Anticipation under 35 U.S.C. § 102 requires the presence in a single prior art disclosure of each and every element of a claimed invention. *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 U.S.P.Q.2D (BNA) 1051, 1053 (Fed. Cir. 1987); *Carella v. Starlight Archery*, 804 F.2d 135, 138, 231 U.S.P.Q. (BNA) 644, 646 (Fed. Cir.), modified on reh'd, 1 U.S.P.Q.2D (BNA) 1209 (Fed. Cir. 1986); *Jamesbury Corp. v. Litton Indus. Prods.*, Inc., 756 F.2d 1556, 1560, 225 U.S.P.Q. (BNA) 253, 256 (Fed. Cir. 1985); *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458, 221 U.S.P.Q. (BNA) 481, 485 (Fed. Cir. 1984); *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548, 220 U.S.P.Q. (BNA) 193, 198 (Fed. Cir. 1983). During examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification. See *In re Graves*, 69 F.3d 1147, 1152, 36 U.S.P.Q.2D (BNA) 1697, 1701 (Fed. Cir. 1995); *In re Etter*, 756 F.2d 852, 858, 225 U.S.P.Q. (BNA) 1, 5 (Fed. Cir. 1985) (en banc).

Here, **De Santis fails to disclose a drill bit that injects medication of claim 14 and claim 19**. Claims 14 recite in relevant parts that the "overall length from a distal tip of the cutting surface to a proximal end of the open notch is greater than a thickness of the hard tissue." Not only does De Santis fail to teach a drill bit with an overall length between the distal tip of the cutting surface to the proximal end of the open notch greater than a thickness of the hard tissue, but De Santis teaches the exact opposite. The drill bit in De Santis is "specifically designed to allow the physician user to extract a sample of tissue." (See C2/L37-39). To that end, the overall length between the distal tip of the cutting surface to the proximal end of the open notch in De

Santis must be less than the thickness of the hard tissue so that the tissue biopsy can be drawn into the biopsy reservoir. (See C10/L2-14 and corresponding Figure 12a). Modifying the drill bit of De Santis with the structure of claim 14 would prevent the drill bit of from extracting a tissue sample, which creates the exact opposite results as the present invention.

Additionally, **the drill bit of De Santis is not capable of performing the intended use of claim 14**. Claim 14 recites that the drill bit is designed to inject medication, and claim 19, which depends on claim 14, recites that the drill bit injects a substance into a bone. Contrary to what the Office claims, the prior art structure of De Santis is not capable of performing the intended use of injecting medication. De Santis teaches a drill bit designed to extract a sample of tissue, while claim 14 recites a drill bit that injects medication. The design and purpose of the drill bit in the current invention and the drill bit in De Santis are not only completely antithetical to one another, but would not work with the same invention. The drill bit in De Santis is designed to have the tissue directly abut the lumen so that it is easier to cut, whereas the drill bit in the current invention is designed to have the tissue reside in the distal portion of the notch away from the first opening so that medication can be injected without tissue blockage impeding the flow of medication. If the prior art structure of De Santis is used, the extended slot 13 would be clogged with tissue and injecting medication would be extremely difficult if not impossible.

In light of the foregoing, the Office has failed to show De Santis discloses each and every element of a claimed invention.

B. REJECTION OF CLAIMS 14, 15, 17, 19 AND 21 AS BEING ANTICIPATED BY SHAW

The Office's rejection of claims 14, 15, 17, 19 and 21 under 35 U.S.C. 102(b) as being anticipated by Shaw (US 5,261,818) should be withdrawn. Again, the Office has failed to show that Shaw discloses each and every element of a claimed invention:

1. Shaw Fails to Disclose the Open Notches of Claim 14

The Office argued that Shaw teaches an open notch by equating the open notch of claim 14 with the co-axial channels 26. (See Office Action, page 2) However, the co-axial channels 26

can not be equated with the open notches of claim 14 as the Applicant specifically defined an open notch to be a hole through the wall of the hollow drill.

"A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as any special meaning assigned to a term is clearly set forth in the specification." (See MPEP 2173.01) The Applicant defined the term "open notch" clearly in the Specification.

> "An alternative design of this invention is a hollow drill bit with an open notch (a small hole through the wall of the hollow drill) located proximal of the distal beveled tip." (See P4/L1-3)

The co-axial channels of Shaw are obviously not small holes punched through the wall of the hollow drill, but are rather grooves that are carved into the sides of the drill. A groove is not the same thing as a hole.

2. Shaw Also Fails to Disclose a Drill Bit of Claim 14.

The Office erroneously equated channel outlets 22 of Shaw with the open notch of claim 14. In fact, the distance from the distal tip of the cutting surface to the proximal end of channel outlets 22 is less than the thickness of the hard tissue (the tooth) that Shaw is designed to drill. The channel outlets 22 are placed "proximal to said working tip 14." (See C2/L32-34 and corresponding Figure 1) Shaw fails to teach, suggest, or motivate "an overall length from a distal tip of the cutting surface to a proximal end of the open notch is greater than the thickness of the hard tissue."

3. Shaw Also Fails to Disclose a Lumen Inside the Shaft that Extends Between First and Second Openings of Claim 14

Claim 14 recites in relevant part that "a lumen inside the shaft that extends between first and second openings." The Applicant agrees that Shaw teaches a shaft 13 with a lumen 18 with a first opening 34 and a second opening 22. However, while lumen 18 connects to second opening 22, lumen 18 fails to connect second opening 22 to first opening 34. Neither the specification nor the drawings of Shaw connect lumen 18 with first opening 34. The specification refers to first opening 34 once in C2/L63-64, explaining how Figure 5 shows how

first opening 34 is located in alternating channels. The opening of Shaw is indeed not connected to lumen 18 as recited in Claim 14.

In addition, Shaw's lumen fails to receives debris entering the first opening as a result of operation of the cutting surface as recited in Claim 14. The Office erroneously once again argued that since there is nothing blocking the first opening 34, lose debris could enter the lumen. However, as explained above, neither the specification nor the drawings of Shaw connect lumen 18 with first opening 34. Therefore, while debris may enter the first opening 34 of Shaw, the debris does not then enter lumen 18 inside shaft 13 as recited in Claim 14.

Thus, the Office has failed to show that Shaw discloses each and every single element of claim 14.

C. REJECTION OF CLAIMS 16 AND 20 AS BEING UNPATENTABLE OVER SHAW.

The Office's rejections of claims 16 and 20 should also be withdrawn for the following reasons.

First, claims 16 and 20 are dependent in one way or another of independent claim 14 and since Shaw clearly does not teach, disclose or even suggest claim 14 from the reasons discussed above, Shaw also does not teach, disclose or even suggest the elements of claims 16 and 20.

For a *prima facie* case, the Office needs to satisfy burden of showing obviousness of the combination only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992).

Claim 16 recites that "the overall length is about 0.10 to 0.125 inches." The specified spacing is to ensure that the length of the bevel cutting surface plus the length of the open notch is greater than the thickness of cortical bone or other hard tissue. Specifically, para [0038] states:

> "The length of the open slot plus the length of the bevel should always be larger than the thickness of the targeted cortical bone and/or hard tissue. For intraosseous

> applications using a 24G drill bit, for example, the slot 18 is about 0.10 to 0.125 inch measured from the distal tip to the proximal end of the slot, as shown as distance 19 in FIGS. 2 and 3b."(emphasis added).

Para [0039] reinforces having a range for the spacing by stating:

> "The length from the sharpened tip to the open notch 38 should always be larger than the thickness of the targeted cortical bone and/or hard tissue. For intraosseous applications using a 24G drill bit, for example, the notch or hole 38 is about 0.10 to 0.20 inch measured from the distal tip to the center of the notch or hole, as shown as distance 39 in FIGS. 9 and 10b." (emphasis added)

The above passages coupled with Figures 5a, 5b, 12a, and 12b, illustrate that having sufficient spacing to overcome the thickness of the hard tissue ensures that the "medication delivery device ...stays unclogged by debris" as fully describe in para [0043] and para [0044]. Therefore, the problem solved by the spacing is to keep the device from becoming clogged with debris during drilling. The advantage of the spacing is that the "...beveled tip stays open during and after drilling through the target tissue..." (emphasis added, para [0044]). Finally, the particular purpose of the spacing is to "...continue [to] serve as a medication delivery passage..." (para [0044]) to administer medication.

The Office argued that the co-axial channels 22 of Shaw extend about 0.19 inches down the length of shaft 18, and that 0.19 inches is "about 0.10 to 0.125 inches." As explained above, the co-axial channels of Shaw can not be equated to the open notch of Claim 14. Furthermore, the 0.19 inches is not an accurate estimation. Channel 22 in Figure 1 is exactly 5/13 the size of the overall length of the drill. Even assuming the length of the drill being the smallest 20 mm that Shaw's specification discloses, the length of channel 22 would be 0.30 inches. Finally, 0.19 inches is not "about 0.10 to 0.125 inches," and 0.30 inches is certainly not "about 0.10 to 0.125 inches." 0.19 inches is 50% greater than the largest distance in the claim, and 0.30 inches is 140% greater than the largest distance in the claim. At most, case law supports a difference of 8%, but surely not a difference of 50% or 140%. See *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968).

Thus, the Office fails to establish a *prima facie* case of obviousness.

Request for Allowance

Claims 14-23 are pending in this application. The Applicant believes that the current pending claims are allowable because independent claim 14, upon which claims 15-23 depend, recites limitations that De Santis and Shaw fail to teach, motivate, or suggest. The Applicant requests allowance of all pending claims.

Respectfully Submitted,
FISH & ASSOCIATES, PC

Date April 7, 2008

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VIII. Claims Appendix

1-13. (cancelled)

14. A drill bit for drilling hard tissue and injecting medication comprising:

a shaft having a proximal end with a first opening, a distal end with a second opening and a beveled cutting surface;

a lumen inside the shaft that extends between first and second openings, and that receives debris entering the first opening as a result of operation of the cutting surface;

an open notch disposed in the shaft, and having a length greater than a diameter of the lumen; and

wherein an overall length from a distal tip of the cutting surface to a proximal end of the open notch is greater than a thickness of the hard tissue.

15. The drill bit of claim 14, wherein the notch is contiguous with the second opening.

16. The drill bit of claim 14, wherein the overall length is about 0.10 to 0.125 inches.

17. The drill bit of claim 14, wherein the notch is axially extended from the second opening.

18. The drill bit of claim 14, wherein the shaft is substantially smooth.

19. A method of injecting a substance into a bone, comprising:

using a drill bit according to claim 14 to drill a hole in the bone; and

injecting the substance into the proximal opening.

20. The method of claim 19, comprising using a hypodermic needle to inject the substance.

21. The method of claim 19, wherein the substance comprises a medication.

22. The drill bit of claim 14, wherein the shaft is disposed in an elongated hub.

23. The drill bill of claim 22, wherein the lumen is extended from proximal and distal ends of the hub.

24. (canceled)

IX. Evidence Appendix

No evidence was submitted pursuant to §§1.130, 1.131, or 1.132.

X. Related Proceedings Appendix

No related proceedings are known to the applicant.